

CLAIMS

1. A directly tabletable gastroresistant spheroid, characterized in that it comprises:

- 5 ➤ a core comprising one or more active principles, directly coated with
- a flexible and deformable film comprising an enteric polymer and a mixture of saturated and/or unsaturated polyglycosylated glycerides whose
- 10 fatty acids contain at least 8 carbon atoms,
- a water-dispersible outer layer comprising at least one disintegrant.

2. The spheroid of claim 1, characterized in that the

15 core comprises one or more active principles selected from those from the group consisting of gastro-intestinal sedatives, antacids, analgesics, anti-inflammatory, coronary vasodilators, peripheral and cerebral vasodilators, antiinfection agents, anti-

20 biotics, antivirals, antiparasitics, anticancer agents, anxiolytics, neuroleptics, central nervous system stimulants, antidepressants, antihistamines, anti-diarrheals, laxatives, nutritional supplements, immuno-

 depressants, hypocholesterolemics, hormones, enzymes,

25 antispasmodics, antianginal agents, medicinal products which influence heart rate, medicinal products used in the treatment of arterial hypertension, antimigraine agents, medicinal products which influence blood

 clottability, antiepileptics, muscle relaxants,

30 medicinal products used in the treatment of diabetes, medicinal products used in the treatment of thyroid dysfunctions, diuretics, anorexigenic agents, antiasthmatics, expectorants, antitussives, muco-

 regulators, decongestants, hypnotics, antinausea

35 agents, hematopoietic agents, uricosuric agents, plant extracts, and contrast agents.

3. The spheroid of either of claims 1 and 2,

characterized in that the active principle is selected from proton pump inhibitors, preferably omeprazole, lansoprazole, pantoprazole, pariprazole, leminoprazole or rabeprazole, in their racemic form or in the form of
5 pure enantiomers, themselves in base form or in the form of alkali metal salts; nonsteroidal anti-inflammatories, preferably diclofenac, in the form of bases or of salts; antibiotics, preferably erythromycin and its derivatives, in the form of bases or of salts.

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4. The spheroid of one of claims 1 to 3, characterized in that the binder is selected from the group consisting of cellulosic polymers, acrylic polymers, povidones, copovidones, polyvinyl alcohols,
15 alginic acid, sodium alginate, starch, pregelatinized starch, sucroses and derivatives thereof, guar gum, polyethylene glycols, and mixtures thereof.

5. The spheroid of one of claims 1 to 4, characterized in that the core optionally comprises a
20 diluent, an antistat and/or a lubricant.

6. The spheroid of one of claims 1 to 5, characterized in that the enteric polymer is selected
25 from the group consisting of cellulose acetate phthalate, hydroxypropylmethylcellulose phthalate, hydroxypropylmethylcellulose succinate phthalate, polyvinyl acetate phthalate, cellulose acetate trimellitate, carboxymethylcellulose and shellac, which
30 are used alone or in a mixture.

7. The spheroid of claim 6, characterized in that the enteric polymer is a methacrylic acid copolymer.

35 8. The spheroid of one of claims 1 to 7, characterized in that the fatty acids of the mixture of saturated and/or unsaturated polyglycosylated glycerides contain from 8 to 18 carbon atoms (C8-C18).

9. The spheroid of claim 8, characterized in that said mixture is a mixture of mono-, di- and triglycerides and of polyethylene glycol monoester and diester, with a molecular weight of between 200 and 1500, and optionally of glycerol and of free PEG, and predominantly comprises palmitostearic acid, said mixture being characterized by a melting point of between 46.0°C and 51.0°C and a hydrophilic/lipophilic balance (HLB) of 13.
10. The spheroid of claim 8, characterized in that said mixture is Gélucire®, in particular Gélucire 50/13.
11. The spheroid of claims 1 to 10, characterized in that the flexible and deformable film optionally comprises a plasticizer selected from the group consisting of triethyl citrate, acetyl tributyl citrate, triacetin, tributyl citrate, diethyl phthalate, polyethylene glycols, polysorbates, and monoacetylated and diacetylated glycerides, preferably triethyl citrate.
12. The spheroid of claims 1 to 11, characterized in that the coating composition optionally comprises a surfactant, an antistat and/or a lubricant.
13. The spheroid of claims 1 to 12, characterized in that the disintegrant is selected from the group consisting of the crosslinked sodium carboxymethyl-cellulose denoted in the art by the term croscarmellose, crospovidone, sodium carboxymethyl starch, and mixtures thereof.
14. The spheroid of claims 1 to 13, characterized in that the dispersible outer layer optionally comprises a binder and an auxiliary substance, in particular mannitol.

15. A method of preparing the spheroids of claims 1 to 14, characterized in that it comprises the following steps:

- 5 ➤ preparing a core comprising one or more active principles and at least one binder;
- coating the cores thus obtained by spraying the coating composition comprising an enteric polymer and a mixture of saturated and/or unsaturated polyglycosylated glycerides whose fatty acids
10 contain at least 8 carbon atoms, preferably from 8 to 18 carbon atoms (C8-C18);
- coating the gastroresistant spheroids with a water-dispersible outer layer comprising at least one disintegrant; and
15 ➤ drying the spheroids.

16. The method of preparing of claim 15, characterized in that the core comprising the active principle is prepared by granulation, by application to neutral
20 substance, or else by extrusion with spheronization.

17. The method of preparing of claims 15 and 16, characterized in that the spheroids are prepared in a fluidized-air bed.
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18. A multiparticulate tablet comprising the spheroids of one of claims 1 to 17.

19. The multiparticulate tablet of claim 18, characterized in that it contains not more than approximately
30 5% by total weight of one or more auxiliary substances.

20. The multiparticulate tablet of either of claims 18 and 19, characterized in that the auxiliary substance
35 is a lubricant, an antistat and/or a permeabilizing agent.

21. The multiparticulate tablet of one of claims 18 to 20, characterized in that it comprises a mixture of

spheroids comprising one or more active principles and of placebo spheroids.

22. A method of preparing multiparticulate tablets of
5 either of claims 18 and 19, characterized in that it comprises the following steps:

- mixing the gastroresistant spheroids with not more than approximately 5% by weight in total of one or more auxiliary substances;
- 10 ➤ tableting the mixture to give a unitary form.